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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,119	03/15/2004	Carsten Neumann	NEUMANN C 1	9186

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1077 Northern Boulevard
Roslyn, NY 11576-1696

EXAMINER

WOODALL, NICHOLAS W

ART UNIT	PAPER NUMBER
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3775

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02/22/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/801,119	Applicant(s) NEUMANN, CARSTEN	
	Examiner Nicholas Woodall	Art Unit 3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5,6,8-10,12,13,17-19 and 21-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5,6,8-10,12,13,17-19 and 21-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/14/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to applicant's amendment received on 12/23/2008.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 29th, 2009 has been entered.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the plug-in connection including a groove, a spring, a mandrel, and a catch seat as disclosed in claim 28 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate

changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The applicant states in the response filed on November 29th, 2009 that Figure 23 shows the limitations of claims, but the examiner does not fully agree with this statement. The figure has the elements labeled, but the examiner is unable to see the spatial relationship between the elements or how the elements cooperate to lock the implant body to the joining plate. For example the examiner is unable to confirm that element 9 is really a type of spring and how that spring works to lock the implant body to the joining plate. Therefore one having ordinary skill in the art would not be able to build the invention based on the specification and figures of this application. The applicant needs to provide at least one figure clearly showing the arrangement of the elements relative to one another and how the mechanism locks the implant body and the joining plate together.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-3, 5, 6, 8-10, 17-19, 21-27, 29, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paponneau (U.S. Publication 2003/0176925) in view of Yeh (U.S. Patent 6,730,088) and Strnad (U.S. Patent 6,296,665).

Paponneau discloses a device comprising an implant body and a joining plate having an outside contour projecting beyond an outside contour of the implant body and is releasably connected with a free end of the implant body in a substantially perpendicular alignment relative to the longitudinal axis of the implant body by an attachment means, wherein the device is inserted between adjacent vertebrae of the spinal column as a substitute for an intervertebral disc. The joining plate has a thickness and includes an opening forming a passage into the implant body adapted to an outside contour of the device formed to be in the center of gravity of the joining plate, a plurality of openings, a ridge disposed around the plurality of passage openings, and cutting blades on the side facing the vertebra. The attachment means are formed by a plug-in connection formed between the joining plate and at the implant body, wherein a groove is formed in the joining plate and retaining clip formed in the free end of the implant body. The sides of the joining plate are oriented at an incline relative to the longitudinal axis up to 5 degrees in flexion, extension, or lateral bending. Paponneau fails to disclose the device further comprising an implant body including a first implant part, a second implant part, and a threaded ring coupled to the second implant part, the device comprising an angle adjustment mechanism between the joining plate and the implant body, the plurality of passage openings extending to an outer edge of the joining plate,

joining plate having a star-shape, the opening of the joining plate being configured outside the center of gravity of the joining plate, one side of the joining plate being enlarged, the joining plate having a thickness corresponding to between 2% and 30% of the height of the implant body, the surface of the joining plate facing the vertebra having a convex shape, and the grooves of the plug-in connection being on the implant body.

Yeh teaches a device comprising an implant body including a first implant part, a second implant part, and a threaded ring comprising a beveled wheel gear connected to the second implant part, wherein the first implant part includes threads engaged with the threaded ring and comprising an angle adjustment mechanism between a joining plate and the implant parts, wherein the angle adjustment mechanism comprising a plurality of ridges and catch seats along the engaged surfaces in order to allow the device to be axially adjustable and to adjust the angle between the joining plate and the implant parts. Strnad teaches a device comprising a joining plate having an enlarged anterior side relative to the posterior side and wherein at least one of the plurality of passage openings extend to an outer edge of the joining plate in order to provide a joining plate having a shape corresponding to the vertebral endplate surface and to facilitate bone growth (column 3 lines 60-62). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Paponneau wherein the implant body further comprises a first implant part, a second implant part, and a threaded ring and the device further comprising an angle adjustment mechanism in view of Yeh and the joining plate having an enlarged side and a plurality of passage openings extending to an outer edge of the joining plate in view of Strnad in order to

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allow the device to be axially adjustable, to adjust the angle between the joining plates and the implant parts, to provide a joining plate having a shape corresponding to the vertebral endplate surface, and to facilitate bone growth. Regarding the opening of the joining plate being configured outside the center of gravity of the joining plate, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the opening of the joining plate outside of the center of gravity of the joining plate, since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70. Regarding the thickness of the joining plate corresponding to between 2% and 30% of the height of at least one of the implant parts and the catch seats of the angle adjustment means being separated by a distance between 10 degrees to 45 degrees, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the joining plate a thickness corresponding to between 2% and 30% of the height of at least one of the implant parts and the catch seats of the angle adjustment means being separated by a distance between 10 degrees and 45 degrees, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding the joining plate having a star-shape and the surface of the joining plate facing the vertebrae to have a convex shape, it would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to provide the joining plate with a star-shape and the surface of the joining plate facing a vertebrae having a convex shape, since applicant has not disclosed that such solve any stated

problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing a joining plate and a surface. In re Dailey and Eilers, 149 USPQ 47 (1966). Regarding the groove of the plug-in attachment means being located on the free end of the implant parts, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the groove of the plug-in attachment means on the free end of the implant parts, since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. In re Einstein, 8 USPQ 167.

6. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paponneau (U.S. Publication 2003/0176925) in view of Yeh (U.S. Patent 6,730,088) further in view of Strnad (U.S. Patent 6,296,665) further in view of Bucher (U.S. Patent 6,171,059).

The combination of Paponneau as modified by Yeh as further modified by Strnad discloses the invention as claimed except for attachment means comprising a groove in the free end of the implant bodies and further comprising a spring mounted in a groove in an opening formed in the joining plate. The combination of Paponneau as modified by Yeh as further modified by Strnad discloses a device comprising an attachment means including a groove located on the joining plate and a retaining clip located on the free end of the implant parts in order to attach the two components together. Bucher teaches a device comprising an attachment means comprising a groove located in a first component and a spring mounted in a groove in an opening of the second component in order to attach the two components together. Because both the combination of

Paponneau as modified by Yeh as further modified by Strnad and Bucher teach devices comprising attachments means, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute one attachment means for the other in order to achieve the predictable results of attaching the two components together.

7. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Paponneau (U.S. Publication 2003/0176925) in view of Strnad (U.S. Patent 6,296,665) and in view of Doty (U.S. Patent 4,599,086).

Paponneau discloses a device comprising an implant body and a joining plate having an outside contour projecting beyond an outside contour of the implant body and is releasably connected with a free end of the implant body in a substantially perpendicular alignment relative to the longitudinal axis of the implant body by a connection means, wherein the device is inserted between adjacent vertebrae of the spinal column as a substitute for an intervertebral disc. The joining plate has a thickness and includes an opening adapted to an outside contour of the device formed to be in the center of gravity of the joining plate, a plurality of openings, a ridge disposed around the plurality of passage openings, and cutting blades on the side facing the vertebra. The connection means is formed by a plug-in connection formed between the joining plate and at the implant body, wherein a groove is formed in the joining plate and retaining clip formed in the free end of the implant body. The sides of the joining plate are oriented at an incline relative to the longitudinal axis up to 5 degrees in flexion, extension, or lateral bending. Paponneau fails to disclose the implant body further

comprising a first implant body and a second implant body axially adjustable relative to each other and the connection means comprising a spring plug-in means and a catch seat to receive the plug-in means. Strnad teaches a device comprising an implant body and a joining plate, wherein the implant body includes a first implant body and a second implant body axially adjustable relative to each other in order to allow the device to be adjusted to better fit between two adjacent vertebral bodies. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Paponneau wherein the implant body includes axially adjustable implant bodies in view of Strnad in order to allow the device to be adjusted to better fit between two adjacent vertebral bodies.

Regarding the connection means comprising a spring plug-in means and a catch seat, Paponneau discloses a device comprising a connection means including a plug-in connection formed between the joining plate and at the implant body, wherein a catch seat, i.e. groove, is formed in the joining plate and a plug-in, i.e. retaining clip, formed in the free end of the implant body in order to connect the two elements relative to each other. Doty teaches a device comprising a first element (18), a second element (12), and a connection means including a spring plug-in (56), a mandrel (52) disposed on an opposite side of the spring plug-in, and a catch seat (64), wherein the spring plug-in are disposed in a groove and are received by the catch seat in order to connect the two elements relative to each other. Because both Paponneau as modified by Strnad and Doty both disclose devices comprising connection means, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute

one connection means for the other in order to achieve the predictable results of connecting the two elements of the device relative to each other.

The device of Paponneau as modified by Strnad as further modified by Doty fails to disclose the spring plug-in to be on the joining plate and the catch seat being located on the free end of one of the implant parts. It would have been obvious to one having ordinary skill in the art at the time the invention was made to place the spring plug-in on the joining plate and the catch seat being located on the free end of one of the implant parts, since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.

Response to Arguments

8. Applicant's arguments filed on November 29th, 2009 have been fully considered but they are not persuasive. The applicant's argument that Papponeau does not disclose an opening in the joining plate for releasable attachment to the implant body forming a connection located outside the center of gravity of the joining plate and is therefore not a simple rearranging of the opening is not persuasive. As discussed in the rejection Papponeau clearly discloses the joining plate includes an opening for releasable attachment to the implant body forming a connection between the joining plate and the implant body, wherein the opening/connection is aligned with the center of gravity of the joining plate. The only limitation that is missing from the Papponeau disclosure is the opening/connection being located outside the center of gravity of the joining plate. In re Japikse states that changing the position of an element is obvious as long as the function of the element is not changed. The examiner believes that

rearranging the opening from the center of the joining plate to a position outside the center of gravity of the joining plate and therefore moving the location of the implant parts would not change the function of the opening, which is to receive the implant parts, or the function of the implant parts, which is to support the loads of the vertebral bodies. To further support this conclusion of obviousness the examiner is providing U.S. Patent 5,916,267, U.S. Patent 6,375,683, and U.S. Patent 6,296,665 to show that it was well known in the art at the time the invention was made to have implant bodies connect to the joining plate at a location outside of the center of gravity of the joining plates. The applicant's argument that the star-shape of the joining plate is more than an obvious matter of design choice is not persuasive. The applicant argues that the specification clearly states that the star-shape configuration for the joining plate allows for an osseous connection between the joining plate and the endplate of the vertebral body. The Papponeau and the Strnad references both disclose that the shape and openings of the joining plates allow for an osseous connection, i.e. bone growth, between the joining plates and the endplates of the vertebral body and can be used with bone growth materials, such as cement. Therefore, configurations of the joining plates in the references solve the exact same problem outlined in the specification of the current application. Furthermore, the specification clearly states that the osseous connection is not limited to the star configuration, but to any shape joining plate that includes openings (see page 7 lines 14-19). Therefore, the star-shape configuration of the joining plate is clearly one of any numerous shapes a person of ordinary skill in the art would find obvious for the purpose of providing a joining plate that forms an osseous

connection with the endplate of a vertebral body. Also, the examiner would like to note that the specification does not provide a specific definition for a star-shaped joining plate. The term "star-shaped" could be interpreted as a circular/spherical shape, such as a real star, or the term "star-shaped" could be interpreted as a shape having a number of pointed ends. The examiner would like to note that U.S. Patent 6,375,683 shows endplates having circular joining plates that could be interpreted as star-shaped.

Conclusion

9. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicholas Woodall whose telephone number is (571)272-5204. The examiner can normally be reached on Monday to Friday 8:00 to 5:30 EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached on 571-272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas Woodall/
Examiner, Art Unit 3775

/Thomas C. Barrett/
Supervisory Patent Examiner, Art
Unit 3775